INFORMATION

The New Amendment to the Food and Drugs Act

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The Durham Humphrey amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 215, 82nd Congress) became fully effective April 6.

To the greatest degree this law affects manufacturers, producers and distributors of drugs in interstate commerce, and pharmacists and others who sell or dispense these drugs to the ultimate user.

The demand for a change in the law was made by pharmacists operating retail stores because of the existing confusion with respect to the labeling of drugs, the gross misuse of the prescription legend by manufacturers, and rulings of the Food and Drug Commissioner regarding refilling prescriptions.

The actual wording of the Federal law and regulations issued pursuant to it made any prescription, unless it was an original prescriptions written by the prescriber, unlawful. No phone prescription even for the simplest drug was lawful and no phone authorization was recognized either for an original order or for a refill. The Administrator subsequently modified this position by stating that confirmation in writing within 72 hours would be acceptable.

In spite of the fact that pharmacists working with physicians to give the patient a maximum service disregarded to some extent these rigid regulations, there were nevertheless numerous instances where the pharmacist got into serious trouble with the law enforcement officers because he was trying to carry out a traditional policy long established as ethical.

The climax to the utterly ridiculous position of the Administrator (at that time Dr. Paul Dunbar) came in an address delivered at the convention of the National Association of Retail Druggists at Atlantic City, in which he said that the refilling of *any* prescription was not in fact the dispensing of a prescription, but actually a sale over the counter of the drug involved. And the suggestion was made that the pharmacist could, if the drug called for was one that could be sold without a prescription, sell it to the patient by merely labeling it with its common name and any directions that might be required in conformity with food and drug law requirements.

This was the straw that really broke the camel's back, and a longsuffering and tolerant retail drug group got up on its hind legs and started to fight.

This prescription question was not the only bad feature of the law. Another just as vexing and troublesome was the question of the use of the prescription legend on drugs. Some manufacturers were using this legend on the simplest of drugs. The use of this legend on calcium carbonate was a striking example of such misuse.

The purpose of the amendment was to clarify and determine which drugs should be dispensed solely on prescription and which could be sold without prescription. The labeling was to be the criterion. The contention was that a drug safe for lay use should not bear the prescription legend, and that one unsafe for use except under professional advice should bear it.

California Pharmaceutical Association believes the physician should be the one to determine the use of all drugs bearing the prescription legend and his authority to the pharmacist should be the controlling factor of their distribution. This condition is provided for in the amended law.

And for the first time in the law an objective definition is given of the kind of drug that should bear the prescription legend. In fact, if it qualifies it *must* bear the legend. That is where the physician comes in. Since the new classification definitely determines the distribution of the drug only on prescription, the physician has a privilege and an obligation.

The privilege is one of complete control, which is given in the interest of safety and public health, and the obligation is to see that the pharmacist has the proper authority to dispense and that he is given instructions regarding refills if refills are intended. The control for use of the drug limited to prescriptions is just as effective with respect to refills as it is to the first order. Within this scope of obligation the patient deserves first consideration, for in the case of a need for continuing medication the patient should be able to obtain his prescription with the least inconvenience to himself.

For the pharmacists, the regulations on this new law make about 12 typed pages. They are not too hard to comply with because the law is fairly clear. As to the basic points of the new law of interest to physicians:

A physician may write or telephone *any* prescription (except a narcotic prescription) to the pharmacist and it is a legal order, requiring no confirmation in writing.

He may, in writing or by telephone, authorize the refilling of *any* prescription (except a narcotic prescription) and it is a legal prescription requiring no confirmation in writing. Under the Federal law, he may, either in written prescription or in oral prescription, give *any* authority he desires regarding the refilling of such prescription—*but in California barbiturates would be excepted from this provision in the Federal law; the California law requires a separate order for each dispensing of any hypnotic drug.*

A physician may give an order or prescription for drugs for a patient, without doing so personally, and the pharmacist can fill such order, if he is satisfied that the order is by "express authority" of the prescriber. Such "express authority" would come through an employee of the physician to whom such instructions were given, and not through a patient.